This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21!

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 51-R-0082
CUSTOMER NUMBER: 33766

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Bioreliance Corporation
14920 Broschart Road
Rockville, MD 20850

Telephone: (301) -738-1000

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY **(Attach additional sheets if necessarv or use APHIS Form 7023A)**

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs		672	1,925		2,597
7. Hamsters		447	891	334	1,672
8. Rabbits		138			138
9. Non-hu nan Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

(b)(6), (b)(7)c

.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*

DATE SIGNED 11.25.08

APHIS FORM 7023 (AUG 91)

(Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

NOV 26 2008 NP

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column e explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: **51-R-0082**

2. Number of animals used in this study. **200-2000 per study based on study design**
   Studies:
   AC07AD.195335.BSV - 50 hamsters
   AC11EV.195334.BSV - 109 hamsters
   AC06SS.195338.BSV - 46 hamsters
   AC06SR.195339.BSV - 51 hamsters
   AB20HF.195336.BSV - 78 hamsters

3. Species (common name): **Hamster**

4. Explain the procedure producing pain and/or distress.

   The pain experienced is due to the development of scrapie clinical signs in hamsters. The In Vivo assay is currently the most sensitive assay for scrapie and the only method accepted by regulatory agencies for scrapie. Regulatory agencies are requiring that manufacturers show the efficacy of their manufacturing process in the removal of possible contaminants. Animals must be held until the terminal stage of the disease is observed, which include generalized tremor, abnormality of gait, ataxia and head bobbing. All clinical signs must be confirmed histopathologically (vacuolization of the brain).

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (for Federally mandated testing, see below)

   See 6. below.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g, APHIS, 9 CFR 113, 102).

   a. **"Federal Bulletin No. 40, 26 February 1994, German Federal Ministry of Health Guidelines on Safety Measures for Minimizing the Risk of transmission of BSE and Scrapie".**
   b. **"WHO Consultation of Medical and other Products in Relation to Human and Animal Transmissible Spongiform Encephalopathies" (Geneva 24-26, March, 1997) and OIE Animal Health Code (May 1997) Concerning BSE.**
   c. **Committee for Proprietary Medicinal Products (CPMP) "Notes for Guidance Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products", (1997).**